

Appl. No. 10/803,126
Docket No. 9183M&
Amdt. dated October 23, 2007
Reply to Office Action mailed on April 27, 2007
Customer No. 27752

REMARKS

Claim Status

Claims 1-4, 8, 9 11, 12 and 14-27 were examined. Claims 1, 14, 15 and 21 are amended, Claim 4 is canceled and Claim 28 is added herein. Accordingly, Claims 1-3, 8-9, 11-12, and 14-28 are currently pending.

Remarks

Claim 1 is amended to further define the present invention wherein the ratio of zinc-containing layered material to pyrithione or a polyvalent metal salt of pyrithione is from about 1:2 to about 3:1. Support for this amendment is found at least at page 6, lines 10-13 of the present specification.

Claim 14 is amended to replace "ZPT" with the phrase "the pyrithione or a polyvalent metal salt of a pyrithione". Support for this amendment is found in Claim 1, as originally filed. The amendment of Claim 14 addresses the 35 U.S.C. 112 rejection of Claim 14 wherein it was found that there is insufficient antecedent basis for the term "ZPT". Applicants respectfully request that the 112 rejection be withdrawn in view of the amendment.

Claim 15 is amended to further define that the zinc-containing layered material comprises layers and comprises gallery ions between the layers. Support for this amendment can be found at least at page 6, lines 18-23 of the present specification.

Claim 21 is amended to further recite that the in-situ reaction product comprises hydroxy-containing basic zinc carbonate. Support for this amendment can be found at least at page 3, lines 19-21, page 51, lines 10-19, and the claims as originally filed.

New Claim 28 is added to further recite that the zinc-containing material of Claim 15 is obtained synthetically or formed in situ in a composition or during a production process. Support for this amendment can be found at least at page 4, lines 28-29 of the present specification.

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No new matter is added herein. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Comments Regarding Withdrawn Rejections

Applicants respectfully thank the Examiner for withdrawing the rejection of Claims 1-4, 8, 9, 11, 12, 14 and 17 over Gavin et al., the rejection of Claim 22 over Biener and Cilley et al., and the rejection of claims 18-21 over Gorman in view of Daley.

It is noted in the outstanding Office Action that a reason for the withdrawal of the rejection over Gavin et al. is that Gavin et al. "do not disclose the source of zinc carbonate." (See Office Action, p. 2). However, Applicants respectfully note the composition recited in claim 1 and the claims dependent therefrom do not specify a zinc carbonate "source" but rather specify that the zinc containing layered material must be a hydroxy-containing basic zinc carbonate. Applicants submit that a zinc containing layered material of hydroxy-containing basic zinc carbonate is not disclosed or suggested by Gavin et al.

Rejection Under 35 USC §102(b) Over WO 01/00151 (Gavin et al.)

Claims 15, 16, 21 and 23-25 are rejected under 35 USC §102(b) as anticipated by International Patent Application No. WO 01/00151 to Gavin et al. (hereinafter "Gavin et al.") as evidenced by the Mineral Willemite.

Gavin et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp. Specifically, the composition of Gavin, et al. includes from about 0.001% to about 10% by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione, from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from the group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts and mixtures thereof and a topical carrier for the anti-microbial active and the metal salt.

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The Office Action states that Gavin et al. discloses the zinc salt of zinc silicate, which is also known as the mineral willemite. The Office Action asserts that since the instant application teaches a non-limited list of natural and synthetic zinc layered materials and Gavin et al. discloses zinc silicate, which has the same common formula for the mineral Willemite, then the zinc silicate of Gavin et al. would inherently have the same augmentation factor of the instantly claimed zinc layered material. Applicants respectfully disagree with this rejection as it is Applicants' position that zinc silicate (or the mineral willemite) is not a zinc containing layered material.

At the outset, Applicants note that Claims 23-25 refer specifically to claim 1, which requires a hydroxy-containing basic zinc carbonate. Since the Examiner accepts that hydroxy-containing basic zinc carbonate is not disclosed or suggested by Gavin et al. (See Office Action mailed April 27, 2007, p. 2), Applicants submit this rejection as applied to claims 23-25 should be withdrawn.

Claims 15 and 16 are directed to a composition having an effective amount of pyrithione or a polyvalent metal salt of a pyrithione and an effective amount of a zinc-containing layered material sufficient to enhance the efficacy of the pyrithione wherein the zinc-containing layered material comprises layers and comprises gallery ions between the layers.

Applicants submit zinc silicate is not a zinc containing layered material (herein after referred to as "ZLM") which comprises layers having gallery ions between the layers. Indeed, zinc silicate is not even listed, mentioned or suggested in the description of ZLM in the present specification. Applicants note the present specification at page 4, lines 24-29 merely discloses that that *many* ZLM's occur naturally as minerals. However, Applicants submit that not *all* naturally occurring zinc minerals are layered materials. As noted at page page 6, lines 18-23 of the present specification, and as recited in amended claim 15, a zinc containing layered material comprises layers having gallery ions located between the layers. Applicants submit that zinc silicate is not a zinc containing layered material as described and claimed herein.

Gavin et al. discloses a myriad of zinc salts, including zinc carbonate and a dozen or so other zinc salts at page 6, lines 1-6 of the reference. In this long list of zinc salts, there is no disclosure or suggestion of the claimed ZLM, which comprises layers having

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gallery ions located between the layers. Accordingly, Claims 15 and 16 are not anticipated by Gavin et al.

Claim 21, as now amended, requires the in-situ reaction product to comprise hydroxy-containing basic zinc carbonate. As previously argued by the Applicants, and accepted by the Examiner (See Office Action mailed April 27, 2007, p. 2), Gavin et al. does not disclose or suggest hydroxy-containing basic zinc carbonate. Accordingly, the rejection as applied to claim 21 is now moot in view of the instant amendment.

Rejection Under 35 USC §103(a) Over EP 1145707 (Iwai et al) in view of WO 01/00151 (Gavin et al.)

Claims 1-4, 8, 9, 11, 12, 14-17 and 23-25 have been rejected under 35 USC §103(a) as being unpatentable over EP 1145707 (hereinafter "Iwai et al.") in view of Gavin et al.

Iwai et al. discloses compositions for external use comprising 0.01-20 wt% of a zinc compound, such as basic zinc carbonate, 0.01-20 wt% of a thiol compound and anionic surfactant. The Office Action asserts that the basic zinc carbonate taught by Iwai et al. would have the same level of augmentation factor as instantly claimed.

The Office Action further asserts that Iwai et al. does not expressly teach a composition wherein the thiol compound is pyrithione, but that one of ordinary skill in the art would have been motivated to add zinc pyrithione, as suggested by Gavin et al., to the composition of Iwai et al. because Iwai et al. suggest adding thiol compounds to the composition but not specifically pyrithione and Gavin et al. cure this deficiency by teaching that zinc pyrithione is suitable for external compositions.

Applicants agree with the Examiner that Iwai et al. does not teach the combination of a pyrithione with a hydroxy-containing basic zinc carbonate. However, Applicants respectfully direct the Examiner's attention to Iwai et al. at page 4, lines 23-26, wherein a dozen or so examples of zinc compounds are listed. Basic zinc carbonate and zinc pyrithione are among those zinc compounds listed in Iwai et al. Further, Examples 24A and 25A comprise zinc pyrithione as a zinc compound. Despite this disclosure of zinc pyrithione within Iwai et al., Applicants submit none of the compositions exemplified in Iwai et al. include the combination of basic zinc carbonate and zinc pyrithione.

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Furthermore, Applicants submit Iwai et al. does not suggest or even allude to such a combination, and certainly does not provide any motivation to one of ordinary skill in the art to combine basic zinc carbonate and zinc pyrithione. Absent impermissible hindsight in view of the instant application, Applicants submit that one of ordinary skill in the art would not have combined basic zinc carbonate and pyrithione in view of Iwai et al. and Gavin et al., taken alone or in any combination, because neither reference discloses or suggests such a combination.

Further, both Iwai et al. and Gavin et al., either taken alone or in any combination, fail to teach or suggest a ratio of zinc-containing layered material to pyrithione or a polyvalent metal salt of pyrithione is from about 1:2 to about 3:1, as recited in the currently amended Claim 1. Therefore, claim 1 and the claims dependent therefrom, are not obvious over Iwai et al. in view of Gavin et al.

Inasmuch as a prima facie case of obviousness has not been established, Applicants respectfully request the Examiner withdraw this rejection.

Rejection Under 35 USC §103(a) Over WO 01/00151 (Gavin et al.) in view of WO 96/25913 (Bhat et al.)

Claims 1-4, 8, 9, 11, 12, 14-17 and 23-25 have been rejected under 35 USC §103(a) as being unpatentable over Gavin et al. in view of WO 96/25913 (hereinafter "Bhat et al.")

Gavin et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp which include a polyvalent metal salt of pyrithione and include a metal ion source, and is discussed in more detail above.

Bhat et al. discloses the use of monophasic zinc hydroxycarbonate as an antimicrobial agent in personal care products, particularly in such products which also contain a surfactant such as soap or a synthetic detergent. Additionally, Applicants respectfully point out that Bhat et al. generally refers to zinc hydroxycarbonate with detergent and/or antidandruff actives like zinc pyrithione in shampoos and hair dressings. See p.8, lines 1-4. However, Bhat et al. fails to teach or suggest the composition as recited in claim 1 and the claims dependent therefrom, since Bhat et al. fails to disclose or suggest the claimed

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amounts and ratios of these components. Additionally, Applicants note that Bhat et al. does not illustrate a specific example of shampoo containing pyrithione and zinc hydroxycarbonate, nor does Bhat et al. even suggest any amount or ratio of the claimed components let alone the claimed amounts and ratio. Absent such an example, specific teaching or suggest, Applicants submit that Bhat et al. taken alone or in any combination with Gavin et al. does not obviate the instantly claimed composition.

The Office Action states Gavin et al. does not expressly teach a composition wherein the zinc salt is a zinc layered material, such as hydroxy-containing basic zinc carbonate. However, the Office action asserts that it would have nevertheless been obvious to one of ordinary skill in the art to add basic zinc carbonate, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention recited in claims 1-4, 8, 9, 11, 12, 14-17 and 23-25. It is the Office Action's position that the basic zinc carbonate taught by Bhat et al. would have the same level of augmentation as the present invention.

Applicants submit Gavin et al. and Bhat et al. fail to establish a prima facie case of obviousness, since both references, either taken alone or in any combination, fail to teach or suggest all the claim limitations of the present invention. Specifically, Gavin et al. and Bhat et al. fail to teach or suggest the ratio of zinc-containing layered material to pyrithione or a polyvalent metal salt of pyrithione is from about 1:2 to about 3:1, as recited in the current Claim 1. Accordingly, all of the claim limitations of the present invention are not taught or suggested by Gavin et al. in view of Bhat et al.

The Office Action asserts that the combination of Gavin et al. with Bhat's zinc hydroxycarbonate containing personal care product formulation would meet the claimed augmentation factor. However, Bhat et al. does not contain any examples of a composition containing the combination of zinc-containing layered material and pyrithione in the instantly claimed ratio.

Inasmuch as a prima facie case of obviousness has not been established, Applicants respectfully request the Examiner withdraw this rejection.

Rejection Under 35 USC §103(a) Over US 4,161,526 (Gorman) in view of US 2003/0044471 (Sakuma et al.)

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Claims 18-22, 26 and 27 have been rejected under 35 USC §103(a) as being unpatentable over US 4,161,526 (hereinafter "Gorman") in view of US 2003/0044471 (hereinafter "Sakuma et al.").

Gorman discloses pyrithione, pyrithione salt or dipyrithione compositions containing the zinc salt of an organic or inorganic acid, zinc hydroxide or zinc oxide or a mixture thereof for prevention or removal of discoloration in said compositions. The Office Action asserts that Gorman does not expressly disclose the process where the addition of a bicarbonate/carbonate salt to the composition that would react in-situ with the zinc salt to produce basic zinc carbonate within a range of between about 1:10 to about 10:1 or forming basic zinc carbonate in an amount from about 0.001% to about 10 % or the narrower ranges of about 0.01% to about 7% or about 0.1% to about 5%.

Sakuma et al discloses an inorganic antibacterial/antifungal agent that includes zinc oxide as a main component and an alkali metallic salt one or more selected from the group consisting of lithium, sodium and potassium hydroxides, hydrogencarbonates and carbonates. Sakuma et al. teaches compositions and methods of making the compositions by mixing 1.0g sodium carbonate with 9.0 g zinc oxide. The Office Action asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the composition of Gorman by adding the sodium carbonate/zinc oxide composition, as suggested by Sakuma et al. to produce the instant invention.

In contrast, Claim 18, and the claims dependent therefrom, relate to a process for preparing a personal care composition comprising hydroxy-containing basic zinc carbonate. The process includes reacting a carbonate or bicarbonate salt that is soluble in the personal care composition with a zinc compound that is soluble or insoluble in the personal care composition. The reaction causes in-situ formation of the carbonate salt with the zinc salt to form basic zinc carbonate in the personal care composition. As recited in dependent Claim 19, the zinc hydroxide is reacted with the sodium carbonate in a molar ratio within a range of between about 1:10 and about 10:1.

Applicants submit that one of ordinary skill in the art would not be motivated to combine Gorman and Sakuma et al. for any reason, and if one were to combine the cited

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references, such a combination would not teach or suggest the instantly claimed invention.

According to Gorman, there was a problem with the discoloration of pyrithione that lead to consumer dissatisfaction and economic loss (see Col. 1, lines 24-28). To overcome this discoloration problem, Gorman added from about 0.01 percent to about 1 percent of the zinc salt of an organic or inorganic acid, zinc hydroxide or zinc oxide or a mixture thereof. (see Col. 1, lines 50-55). In contrast, Sakuma et al. sought to provide an inorganic antibacterial/antifungal agent that has distinguished multiple functions with respect to antibacterial and antifungal activities. Sakuma et al. purported to achieve this product by utilizing a combination of zinc oxide with an alkali metallic salt.

Applicants submit one of ordinary skill in the art would not modify Gorman, who sought to improve the discoloration of pyrithione, with the teaching of Sakuma et al. Specifically, one of ordinary skill in the art has no motivation to combine the teaching of Gorman with the teaching of Sakuma et al., since both references seek to solve two separate and distinct problems, i.e. one reference purports to solve a problem associated with the color of a pyrithione product, while the other reference seeks to provide an inorganic antibacterial/antifungal agent that has distinguished multiple functions. Therefore, there is no motivation to combine the teachings of Gorman with the teaching of Sakuma et al.

Inasmuch as a prima facie case of obviousness has not been established, Applicants respectfully request the Examiner withdraw this rejection.

Rejection Under 35 USC §103(a) Over US 2003/0044471 (Sakuma et al.)

Claims 22, 26 and 27 are rejected under 35 USC §103(a) as being unpatentable over Sakuma et al.

Sakuma et al discloses an inorganic antibacterial/antifungal agent that includes zinc oxide as a main component and an alkali metallic salt one or more selected from the group consisting of lithium, sodium and potassium hydroxides, hydrogencarbonates and carbonates. Sakuma et al. teaches compositions and methods of making the compositions by mixing 1.0g sodium carbonate with 9.0 g zinc oxide.

The Office Action asserts that Sakuma et al. does not expressly teach a process that causes in situ formation of basic zinc carbonate in an amount from about 0.001% to

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about 10% or the narrow ranges of the narrower ranges of about 0.01% to about 7% or about 0.1% to about 5%. Further, the Office Action asserts that Sakuma et al. does not expressly teach a personal care composition selected from the group consisting of shampoo, soap or skin care medicament. Nevertheless, the Office Action asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to perform a process that causes in situ formation of basic zinc carbonate in an amount of from about 0.001% to about 10% and produce the instant invention since it is merely a matter of routine optimization by one of ordinary skill in the art to arrive at the instantly claimed amounts of basic zinc carbonate.

Applicants respectfully disagree and submit that Sakuma et al. fail to establish a prima facie case of obviousness. Specifically, Sakuma et al. fails to teach or suggest all the claim limitations of the present invention. It would not be merely a matter of routine optimization by one of ordinary skill in the art to arrive at the instantly claimed amounts of basic zinc carbonate. Therefore, one of skill in the art would have no basis from the teachings of Sakuma et al. with regard to how to arrive at the instantly claimed amounts of basic zinc carbonate.

Inasmuch as a prima facie case of obviousness has not been established, Applicants respectfully request the Examiner withdraw this rejection.

The Double Patenting Rejection

I. Claims 1, 5-9, and 23-25 are provisionally rejected on the grounds of nonstatutory obvious-type double patenting as being unpatentable over claims 1-3, 5, 14-17 and 23-24 of copending Application No. 10/802,166.

Claim 1 of Application 10/802,166 is directed to a composition comprising from about 0.001% to about 10% of a zinc-containing layered material; from about 2% to about 50% of a surfactant including a surfactant with an anionic functional group; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

In contrast, the instant invention is directed to a composition comprising

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from about 0.01 weight% to about 5 weight%, based on the total weight of the composition, of pyrithione or a polyvalent metal salt of a pyrithione; from about 0.001 weight% to about 10 weight%, based on the total weight of the composition, of a zinc-containing layered material which provides an augmentation factor greater than 1 wherein the zinc-containing layered material comprises hydroxy-containing basic zinc carbonate.

The currently claimed invention is not directed to or required to have a relative zinc lability of greater than about 15% for a zinc-containing layered material. Further, the '166 composition is not directed to or required to have a composition containing an augmentation factor greater than 1. The Office Action has asserted that the same material, basic zinc carbonate, is disclosed by Applicant to have both of the properties of relative zinc lability and augmentation. Thus these features are inherent in basic zinc carbonate and would be present no matter where basic zinc carbonate might be.

However, Applicants respectfully point out that these 2 claim sets are patentable distinct. Augmentation and Relative Zinc lability are two distinct components. The term "augmentation factor" is defined in the instant specification. Specifically, "augmentation factor" is the ratio of the MIC (minimum inhibitory concentration) with and without an augmenting agent (at a specified concentration) (page 28, lines 14-16 of the instant application).

In contrast "zinc lability" is a measure of the chemical availability of zinc ions. Soluble zinc salts that do not complex with other species in solution have a relative zinc lability, by definition, of 100%. The use of partially soluble forms of zinc salts and/or incorporation in a matrix with potential complexants generally lowers the zinc lability substantially below the defined 100% maximum (page 30, lines 11 – page 31, lines 1-9 of the '166 application). Therefore, the terms "augmentation factor" and "zinc lability" are two patentably distinct concepts. Accordingly the instant claims and those of copending Application 10/802,166 are patentably distinct.

Applicants respectfully request reconsideration and withdrawal of this nonstatutory obviousness-type double patenting.

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Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC § 112, 102 and 103. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-3, 8-9, 11-12, and 14-28 is requested.

Respectfully submitted,
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